

Sheet 1 of 6

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.:

SERIAL NO.:

AL01132K

09/760,588

INFORMATION DISCLOSURE STATEMENT  
BY APPLICANT

APPLICANT:

M.B. Affrime, et al.

FILING DATE:

01/16/2001

GROUP:

1614

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
cm	AA	6,521,254 B2	02/18/2003	Weinstein, et al	424	468	
	AB	6,514,520 B2	02/04/2003	Munayyer, et al	424	439	
	AC	6,506,767 B1	01/14/2003	Schumacher, et al	514	290	
	AD	6,132,758	10/17/2000	Munayyer, et al	424	439	
	AE	6,100,274	08/08/2000	Kou	514	290	
	AF	6,051,585	04/18/2000	Weinstein, et al	514	335	
	AG	5,939,426	08/17/1999	McCullough	514	290	
	AH	5,900,421	05/04/1999	Handley, et al.	514	290	
	AI	5,731,319	03/24/1998	Aberg, et al.	514	290	
	AJ	5,595,997	01/21/1997	Aberg, et al.	514	290	
	AK	5,476,856	12/19/1995	Carceller, et al	514	290	
	AL	5,407,941	04/18/1995	Carceller, et al	514	290	
	AM	5,314,697	05/24/1994	Kwan, et al.	424	480	
	AN	5,100,675	03/31/1992	Cho, et al.	424	468	
	AO	5,089,496	02/18/1992	Piwinski, et al.	514	253	
	AP	5,019,591	05/28/1991	Gardner, et al.	514	461	
	AQ	4,990,535	02/05/1991	Cho, et al.	514	556	
	AR	4,906,647	03/06/1990	Kouchiwa, et al	514	356	
	AS	4,863,931	09/05/1989	Schumacher, et al.	514	290	
	AT	6,270,796 B1	08/07/2001	Weinstein, et al	424	457	
	AU	4,804,666	02/14/1989	Piwinski, et al..	514	278	

## FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
cm	AV	0 264 259 A1	04/20/1988	European Patent Office	A 61 K	31/44		
	AW	0 288,640 A1	11/02/1988	European Patent Office	A61K	31/445		
	AX	0 396,404 A1	11/07/1990	European Patent Office	A61K	31/445		
	AY	0 396,404 B1	02/16/1994	European Patent Office	A61K	31/445		
	AZ	0 577 957 A1	01/12/1994	European Patent Office	C07D	401/00		
	BA	WO 85/03707	08/29/1985	WIPO				
	BB	WO 92/00293	01/09/1992	WIPO				

## OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

cm	BC	Andersen, et al., "Adverse drug interactions clinically important for the dermatologist", Arch Dermatol, April, 1995, Vol.131, pp. 468-473.
	BD	Babe, et al., "Histamine, Bradykinn, and their Antagonists" in The Pharmacological Basis of Therapeutics (9 <sup>th</sup> edition), The McGraw-Hill Co. Inc., pp. 581-599 (1996).
	BE	Barnett, et al., "Pharmacology of Non-Sedating H 1 Antihistamines", <u>New Perspectives in Histamine Research</u> , Birkhauser Verlag Basel, pp. 181-196 (1991).

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TECH CENTER 1600/2900



FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AL01132K		SERIAL NO.: 09/760,588		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT: M.B. Affrime, et al.				
				FILING DATE: 01/16/2001		GROUP: 1614		
U.S. PATENT DOCUMENTS								
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE	
Cmm ↓	BF	4,783,465	11/08/1988	Sunshine, et al.	514	255		
	BG	4,777,170	10/11/1988	Heinrich	514	226.2		
	BH	4,731,447	03/15/1988	Schumacher, et al.	546	93		
	BI	4,659,716	04/21/1987	Villani, et al.	514	290		
	BJ	4,552,899	11/12/1985	Sunshine, et al.	514	568		
	BK	4,371,516	02/01/1983	Gregory, et al.	424	22		
	BL	4,282,233	08/04/1981	Vilani	424	267		
	BM	4,008,796	02/22/1977	Aylon	198	460		
	BN	3,940,485	02/24/1976	Levinson, et al.	424	250		
	BO	3,916,899	11/04/1975	Theeuwes, et al.	128	260		
	BP	3,845,770	11/05/1974	Theeuwes, et al.	128	260		
	FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO	
Cmm ↓	BQ	WO 92/11034	07/09/1992	WIPO				
	BR	WO 92/20377	11/26/1992	WIPO				
	BS	WO 96/20708	07/11/1996	WIPO				
	BT	WO 96/16641	06/06/1996	WIPO				
	BU	WO 98/34614	08/13/1998	WIPO				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
Cmm ↓	BV	Berge, et al., "Pharmaceutical Salts", J. of Pharm. Sciences, January, 1977, Vol. 66, No.1, pp. 1-19.						
	BW	Berthon, et al., "In Vitro inhibition, by loratadine and descarboxyethoxyloratadine, of histamine release from human basophils, and of histamine release and intracellular calcium fluxes in rat basophilic leukemia cells (RBL-2H3)", Biochem. Pharm., 1994, Vol. 47, No.5, pp. 789-794.						
	BX	Blaug, et al., "Interaction of dextroamphetamine sulfate with spray-dried lactose", J. of Pharm. Sciences, November, 1972, Vol. 61, No.11, pp. 1770-1775.						
	BY	Brandes, et al., "Enhanced cancer growth in mice administered daily human-equivalent doses of some H1-antihistamines: predictive in vitro correlates", J. of the National Cancer Inst., May 18, 1994, Vol. 86, No.10, pp. 770-775.						
	BZ	Brandes, et al., "Stimulation of malignant growth in rodents by antidepressant drugs at clinically relevant doses", Cancer Research, July 1, 1992, Vol. 52, pp. 3796-3800.						
EXAMINER  Cmm				DATE CONSIDERED  9-16/18/03				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.								

MAY 14 2003  
PATENT AND TRADEMARK OFFICE

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AL01132K	SERIAL NO.: 09/760,588
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use several sheets if necessary)</i>				APPLICANT: M.B.Affrime, et al.	
				FILING DATE 01/16/2001	GROUP: 1614

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
cm	CA	3,598,123	08/10/1971	Zaffaroni	128	268	
	CB	3,536,809	10/27/1970	Applezweig	424	28	

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
cm	CC	WO 00/2560	01/20/2000	PCT International			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

TECH CENTER 1600 2900	CD	Brion, et al., "Evaluation of the antimuscarinic activity of atropine, terfenadine and mequitazine in healthy volunteers", Br. J. Clin. Pharmac. 1988, Vol. 25, pp.27-32.
	CE	Carmeliet, "Voltage- and Time-Dependent Block of the Delayed K <sup>+</sup> Current in Cardiac Myocytes by Dofetilide", The J. of Pharm. And Experimental Therapeutics, 1992, Vol. 262, No. 2, pp. 809-817.
	CF	Castello, et al., "Discoloration of tablets containing amines and lactose", J. of Pharm. Sciences, February, 1962, Vol. 51, No.2, pp. 106-108.
	CG	Cheung, et al., "Investigation of anti-motion sickness drugs in the squirrel monkey", J. Clin. Pharmacol, 1992, Vol. No. 32, pp. 163-175.
	CH	Clissold, et al., "Loratadine: A preliminary review of its pharmacodynamic properties and therapeutic efficacy", Drugs, 1989, Vol. 37, pp. 42-57.
	CI	Cooke, "Glycopyrrolate in bladder dysfunction", SA Medical Journal, January 1, 1983, p. 3.
	CJ	Craft, "Torsade de pointes after astemizole overdose", Br. Medical Journal, 1986,, Vol. 292, p. 660.
	CK	Dorje, et al., "Antagonist Binding Profiles of Five Cloned Human Muscarinic Receptor Subtypes", The J. of Pharm. And Experimental Therapeutics, 1991, Vol. 256, pp. 727-733.
	CL	Drug Facts and Comparisons, 1998 Ed., Facts and Comparisons, St. Louis, Missouri, p. 2832.
	CM	Ebert, "Soft elastic gelatin capsules: a unique dosage form", Pharmaceutical Technology, 1977, pp. 44-50.
	CN	Gengo, "Dilemma: Antihistamine selection: Use vs. Side effects", U.S. Pharmacist, November, 1990, pp. 59-92.
	CO	Hartauer, et al., A Comparison of Diffuse Reflectance FT-IR Spectroscopy and DSC in the Characterization of a Drug-Excipient Interaction, "Drug Development and industrial Pharmacy", 1991, Vol. 17, No. 4, pp. 617-630.
	CPI	Herzog, et al., "Urinary Incontinence: medical and Psychosocial Aspects", <u>Annual Review of Gerontology and Geriatrics</u> , 1989, Vol. 9, pp. 74-119.
	CQ	Hilbert, et al., "Pharmacokinetics and Dose Proportionality of Loratadine", J. Clin. Pharmacol. 1987, Vol. 27, pp. 694-98.
	CR	Housley, et al., "Histamine and related substances influence neurotransmission in the semicircular canal", Hearing Research, May 1, 1988, Vol. 35, pp. 87-97.
CS	Jankowski, et al., "Effect of Terfenadine on Nnasal Provocation", Int. Arch. Allergy Immunolog., 1993, Vol. 101, pp. 311-317.	
CT	Kaliner, "Nonsedating Antihistamines: Pharmacology, Clinical Efficacy and Adverse Effects", American Family Physician, March, 1992, Vol. 45, No. 3, pp.1337-1342.	
CU	Kleine-Tebbe, et al., "Inhibition of IgE- and non-IgE-mediated histamine release from human basophil leukocytes in vitro by a histamine H1-antagonist, desethoxycarbonyl-loratadine", J. Allergy Clin. Immunol., 1994, Vol. 93, pp. 494-500.	
CV	Knowles, "Astemizole and Terfenadine-Induced Cardiovascular Effects", The Canadian J. of Hospital Pharmacy, February, 1992, Vol. 45, No. 1, pp. 33 & 37.	

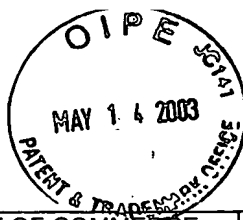
EXAMINER  cm	DATE CONSIDERED  9/16-18/03
--------------------	-----------------------------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Sheet 4 of 6

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AL01132K		SERIAL NO.: 09/760,588	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT: M.B. Affrime, et al.			
				FILING DATE: 01/16/2001		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	CW	Kohl, et al., "Lack of Effects of Astemizole on Vestibular Ocular Reflex, Motion Sickness, and Cognitive Performance in Man", Aviation, Space, and Environmental Medicine, December, 1987, pp. 1171-1174.					
	CX	Kohl, et al., "New Pharmacologic Approaches to the Prevention of Space/Motion Sickness", J. Clin. Pharmacol., 1991, Vol. 31, pp. 934-946.					
	CY	Kohl, et al., "Control of Nausea and autonomic dysfunction with terfenadine, a peripherally acting antihistamine", Aviation, Space and Environmental Medicine, May, 1991, pp. 392-396.					
	CZ	Kubo, et al., "Antimuscarinic Effects of Antihistamines: Quantitative Evaluation by Receptor-Binding Assay", Japan J. Pharmacol., 1987, Vol. 43, pp. 277-282.					
	DA	Lathers, et al., "Pharmacology in space: Part 2. Controlling motion sickness", TiPS, June, 1989, Vol. 10, pp. 243-250.					
	DB	Levin, et al., "Direct Measurement of the Anticholinergic Activity of a Series of Pharmacological Compounds on the Canine and Rabbit Urinary Bladder", The J. of Urology, August, 1982, Vol. 128, pp. 396-398.					
	DC	Lunde, "Antihistamines", Side Effects of Drugs Annual 14, Elsevier Science Publishers B.V., 1990, pp. 135-138.					
	DD	Lunde, "Antihistamines", Side Effects of Drugs Annual 12; A Worldwide Yearly Survey of New Data and Trends, Elsevier Science Publishers B.V., 1998, pp. 142-143.					
	DE	Massad, et al., "The Pharmacokinetics of Intravesical and Oral Oxybutynin Chloride", The J. of Urology, August, 1992, Vol. 148, pp. 595-597.					
	DF	McCue, "Safety of Antihistamines in the Treatment of Allergic Rhinitis in Elderly Patients", Arch. Fam. Med., September, 1996, Vol. 5, pp. 464-468.					
	DG	Miadonna, et al., "Inhibitory Effect of the H1 Antagonist Loratadine on Histamine Release from Human Basophils", Int. Arch. Allergy Immunol., 1994, Vol. 105, pp. 12-17.					
	DH	Mirakhur, et al., "Glycopyrrolate: Pharmacology and Clinical Use", Anaesthesia, 1983, Vol. 38, pp. 1195-1203.					
	DI	Mitchelson, "Pharmacological Agents Affecting Emesis: A Review (Part II)", Drugs, 1992, Vol. 43, No. 4, pp. 443-463.					
	DJ	Muskat, et al., "The Use of Scopolamine in the Treatment of Detrusor Instability", The J. of Urology, 1996, Vol. 156, pp. 1989-1990.					
EXAMINER  cm				DATE CONSIDERED  9-16/18/03			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

TECH CENTER 1600/2900

Sheet 5 of 6

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: AL01132K		SERIAL NO.: 09/760,588	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT: M.B. Affrime, et al.			
				FILING DATE: 01/16/2001		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
cm	DK	Nelemans, "Antiallergic and antitussive drugs", Side Effects of Drugs Annual 12, Elsevier Science Publishers B.V., 1988, pp. 144-147.					
	DL	Nomeir, et al., "Influence of Food on the Oral Bioavailability of Loratadine and Pseudoephedrine from Extended-Release Tablets in Healthy Volunteers", J. Clin. Pharm, 1996, Vol. 36, No. 10, pp. 923-930.					
	DM	Parkinson, et al., "Evaluation of Loratadine as an Inducer of Liver Microsomal Cytochrome P450 in Rats and Mice", Biochemical Pharmacology, 1992, Vol. 43, No. 10, pp. 2169-2180.					
	DN	Peggs, et al., "Antihistamines: The Old and the New", American Family Physician, August, 1995, Vol. 52, No. 2, pp. 593-600.					
	DO	Petrin, "Bewegungskrankheit und ihre Therapie/ Eine Ubersicht (Motion Sickness and its Treatment)", Schweiz, Rundschau Med., 1974, (PRAXIS) 63, pp. 79-81.					
	DP	Quercia, et al., "Focus on Loratadine: A new second-generation nonsedating H1-receptor antagonist", Hosp. Formul., February 1993, Vol. 28, pp. 137, 138, 141, 142, 144, 149, & 153.					
	DQ	Remington's Pharmaceutical Sciences. 18th Ed, Alfonso R. Gennaro, Mack Publishing Company, Easton, PA, 1990, pp. 1519-1520.					
	DR	Remington's Pharmaceutical Sciences. 18th Ed, Alfonso R. Gennaro, Mack Publishing Company, Easton, PA, 1990, pp. 1527-1529					
	DS	Resnick, "Urinary incontinence", The Lancet, July 8, 1995, Vol. 346, pp. 94-99.					
	DT	Roman, et al., "Loratadine-A Review of Recent Finding in Pharmacology Pharmacokinetics, Efficacy, and Safety, with a Look at its Use in Combination with Pseudoephedrine", Clin. Reviews in Allergy, 1993, Vol. 11, pp. 89-110.					
	DU	Simons, "H1-Receptor Antagonists Comparative Tolerability and Safety", Drug Safety, 1994, Vol. 10, No. 5, pp. 350-380					
	DV	Sunahara, et al., "Pharmacological interventions for motion sickness: Cardiovascular Effects", Aviation, Space and Environmental Medicine, September, 1987, pp. A270-A276.					
	DW	Temple, et al., "Loratadine, an Antihistamine, Blocks Antigen-and Ionophore-Induced Leukotriene Release from Human Lung In Vitro", Prostaglandins, 4/1988, 35(4):549-554.					
	DX	Van Cauwenberge, "New Data on the Safety of Loratadine", Drug Invest., 1992, Vol. 4, No. 4, pp.283-291.					
DY	Van Peer, et al., "Ketoconazole Inhibits Loratadine Metabolism in Man", Beers, Belgium, Abstract 1234, p. 34.						
	DZ	Wade, et al., Handbook of Pharmaceutical Excipients (2 <sup>nd</sup> edition), American Pharmaceutical Association and Pharma Press, Royal Pharma. Society of G. Britain, 1994, pp. 257&259.					
EXAMINER  cm				DATE CONSIDERED  9-16/18/03			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

Sheet 6 of 6

FORM PTO-1449		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO.: A101132K		SERIAL NO.: 09/760,588	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)				APPLICANT: M.B. Affrime, et al.			
				FILING DATE: 01/16/2001		GROUP: 1614	
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
	EA	Wein, "Pharmacology of Incontinence", Urologic Clinics of North America, August, 1995, Vol. 22, No. 3, pp. 557-577.					
	EB	Wirth, et al., Maillard Reaction of Lactose and Fluoxetine Hydrochloride, a Secondary Amine, Journal of Pharmaceutical Sciences, Jan. 1998, Vol. 87, No. 1, pp. 31-39.					
	EC	Wood, "Antimotion Sickness and Antiemetic Drugs", Drugs, 1979, Vol. 17, pp. 471-479.					
	ED	Wood, et al., "Mechanisms of Antimotion Sickness Drugs", Aviation, Space, and Environmental Medicine, September 1987, pp. A262-A265.					
	EE	The United States Pharmacopeia, The United States Formulary, United States Pharmacopeial Convention, Inc., Rockville, MD. 1989, p. 1990.					
	EF	Yarker, et al., "Oxybutynin. A Review of its Pharmacodynamic and Pharmacokinetic Properties, and its Therapeutic Use in Detrusor Instability", Drugs and Aging, 1995, Vol. 6, No. 3, pp. 243-262					
	EG	Zhong, et al., "HPLC-Determination of Loratadine and its active metabolite descarboethoxyloratadine in human plasma", Pharmazie, 1994, Vol. 49(H. 10), pp. 736-739.					
EXAMINER					DATE CONSIDERED		
					9-16/18/03		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							